safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 522.1662a is amended by revising paragraph (h)(2) to read as follows:

§ 522.1662a Oxytetracycline hydrochloride injection.

* * * * *

(h) * * *

(2) *Sponsors.* See 054273 in § 510.600(c) of this chapter for use of 50 and 100 milligrams/milliliter solution, and see No. 057319 in § 510.600(c) for use of 100 milligrams/milliliter solution.

* * * * *

Dated: September 1, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 95–23250 Filed 9–19–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Cyclosporine Ophthalmic Ointment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Schering-Plough Animal Health Corp. The NADA provides for use of cyclosporine ophthalmic ointment for treatment of chronic keratoconjunctivitis sicca in dogs.

EFFECTIVE DATE: October 20, 1995.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1617.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., P.O. Box 529, Galloping Hill Rd., Kenilworth, NJ 07033, filed NADA 141–052, which provides for use of Optimmune® (0.2 percent cyclosporine, USP) Ophthalmic Ointment for treatment of chronic keratoconjunctivitis sicca in dogs. The drug product is available on a prescription basis. The NADA is approved as of August 2, 1995, and the regulations are amended in part 524 (21 CFR part 524) by adding new § 524.575 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning August 2, 1995, because no active ingredient (including any ester or salt of the active ingredient) of the drug has been approved in any other application under section 512(b)(1) of the act.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR part 524

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. New § 524.575 is added to read as follows:

§ 524.575 Cyclosporine ophthalmic ointment.

(a) *Specifications.* Each gram of ointment contains 2 milligrams of cyclosporine.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Apply a 1/4-inch strip of ointment to the affected eye(s) every 12 hours.

(2) *Indications for use.* For treatment of chronic keratoconjunctivitis sicca in dogs.

(3) *Limitations.* Place ointment directly on cornea or into the conjunctival sac. Safety of use in puppies, pregnant or breeding animals has not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: September 1, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 95–23247 Filed 9–19–95; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF DEFENSE

Department of the Army

32 CFR Part 505

[Department of the Army Reg. 340-21]

Department of the Army Privacy Program

AGENCY: Department of the Army, DoD.

ACTION: Final Rule.

SUMMARY: The Department of the Army is revising an existing exemption rule. The exemption rule is for the system of records notice identified as A0381–100bDAMI, entitled Technical Surveillance Index.

EFFECTIVE DATE: November 1, 1994.

FOR FURTHER INFORMATION CONTACT: Ms. Pat Turner at (602) 538–6856 or DSN 879–6856.

SUPPLEMENTARY INFORMATION: *Executive Order 12866.* The Director, Administration and Management, Office of the Secretary of Defense has determined that this Privacy Act rule for the Department of Defense does not constitute 'significant regulatory action.' Analysis of the rule indicates that it does not have an annual effect on the economy of $100 million or more; does not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; does not materially alter the budgetary impact of entitlement, grants, user fees, or loan programs or the right and obligations of recipients thereof; does not raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866 (1993).

Regulatory Flexibility Act of 1980. The Director, Administration and Management, Office of the Secretary of Defense certifies that this Privacy Act rule for the Department of Defense does not have significant economic impact on a substantial number of small entities because it is concerned only with the administration of Privacy Act systems of records within the Department of Defense.

Paperwork Reduction Act. The Director, Administration and Management, Office of the Secretary of Defense, certifies that this Privacy Act rule for the Department of Defense imposes no information requirements beyond the Department of Defense and that the information collected within the Department of Defense is necessary and consistent with 5 U.S.C. 552a, known as the Privacy Act of 1974.

List of Subjects in 32 CFR Part 505

Privacy.

Accordingly, the Department of the Army revises 32 CFR part 505 as follows:

1. The authority citation for 32 CFR part 505 continues to read as follows:

Authority: Pub. L. 93–597, 88 Stat. 1896 (5 U.S.C. 552a)

2. Section 505.5(e), paragraph ag. is revised as follows:

* * * * *

(e) * * *

ag. *System identifier and name:* A0381-l00bDAMI, Technical Surveillance Index.

(1) *Exemption.* This system of records may be exempt from the provisions of 5 U.S.C. 552a(c)(3), (d)(1) through (d)(5), (e)(1), (e)(4)(G), (e)(4)(H), and (e)(4)(I).

(2) *Authority.* 5 U.S.C. 552a(k)(1), (k)(2) or (k)(5).

(3) *Reasons.* From subsection (c)(3) because disclosing the identities of agencies to which information from this system has been released could inform the subject of an investigation of an actual or potential criminal violation or intelligence operation; of the existence of that investigation or operation; of the nature and scope of the information and evidence obtained as to his/her activities or of the identify of confidential sources, witnesses, and intelligence or law enforcement personnel and could provide information to enable the subject to avoid detection or apprehension. Granting access to such information could seriously impede or compromise an investigation; endanger the physical safety of confidential sources, witnesses, intelligence or law enforcement personnel, and their families; lead to the improper influencing of witnesses; the destruction of evidence or the fabrication of testimony and disclose investigative techniques and procedures. In addition, granting access to such information could disclose classified and sensitive sources and operational methods and could constitute an unwarranted invasion of the personal privacy of others.

From subsection (d)(1) through (d)(5) because granting access to records in this system of records could inform the subject of an investigation of an actual or potential criminal violation; of the existence of that investigation; of the nature and scope of the information and evidence obtained as to his/her activities; or of the identity of confidential sources, witnesses and intelligence or law enforcement personnel and could provide information to enable the subject to avoid detection or apprehension. Granting access to such information could seriously impede or compromise an investigation; endanger the physical safety of confidential sources, witnesses, intelligence or law enforcement personnel and their families; lead to the improper influencing of witnesses; the destruction of evidence or the fabrication of testimony and disclose investigative techniques and procedures. In addition, granting access to such information could disclose classified, sensitive sources and operational methods and could constitute an unwarranted invasion of the personal privacy of others.

From subsection (e)(1) because it is not always possible to detect the relevance or necessity of specific information in the early stages of an investigation or operation. Relevance and necessity are often questions of judgment and timing, and it is only after the information is evaluated that the relevance and necessity of such information can be established. In addition, during the course of the investigation or operation, the investigator may obtain information which is incidental to the main purpose of the investigative jurisdiction of another agency. Such information cannot readily be segregated. Furthermore, during the course of the investigation or operation, the investigator may obtain information concerning violation of laws other than those which are within the scope of his/her jurisdiction. In the interest of effective intelligence operations and law enforcement, criminal law enforcement investigators and military intelligence agents should retain this information, since it can aid in establishing patterns of criminal or intelligence activity and can provide valuable leads for other law enforcement or intelligence agencies.

From subsections (e)(4)(G) and (e)(4)(H) because this system of records is being exempt from subsections (d) of the Act, concerning access to records, these requirements are inapplicable to the extent that this system of records will be exempt from subsections (d)(1) through (d)(5) of the Act. Although the system would be exempt from these requirements, the Deputy Chief of Staff for Intelligence and the U.S. Army Criminal Investigations Command have published information concerning its notification, access, and contest procedures for their respective areas because, under certain circumstances, the Deputy Chief of Staff for Intelligence or the U.S. Army Criminal Investigations Command could decide it is appropriate for an individual to have access to all or a portion of his/her records in this system of records.

From subsection (e)(4)(I) because it is necessary to protect the confidentiality of the sources of information, to protect the privacy and physical safety of confidential sources and witnesses and to avoid the disclosure of investigative techniques and procedures. Although the system will be exempt from this requirement, the Deputy Chief of Staff for Intelligence and the U.S. Army Criminal Investigations Command have

published such a notice in broad, generic terms.

* * * * *

Dated: September 13, 1995.

L. M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 95–23238 Filed 9–19–95; 8:45 am]

BILLING CODE 5000–04–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 81

[KY89–1–7168; FRL–5297–6]

Designation of Areas for Air Quality Planning Purposes; Commonwealth of Kentucky: Correction to the Boundary of the Kentucky Portion of the Louisville Moderate Ozone Nonattainment Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is correcting the boundaries of the Kentucky portion of the Louisville moderate ozone (O_3) nonattainment area, pursuant to Section 110(k)(6) of the Clean Air Act (the Act). The boundary of the Louisville moderate O_3 nonattainment area (nonattainment area) is being revised to include additional sources that contribute to violation of the O_3 National Ambient Air Quality Standard (NAAQS).

EFFECTIVE DATE: This final rule will be effective October 5, 1995.

ADDRESSES: Copies of the documents relative to this action are available for public inspection during normal business hours at the following locations. The interested persons wanting to examine these documents should make an appointment with the appropriate office at least 24 hours before the visiting day.

Environmental Protection Agency, Region 4 Air Programs Branch, 345 Courtland Street, NE, Atlanta, Georgia 30365.

Division for Air Quality, Department for Environmental Protection, Natural Resources and Environmental Protection Cabinet, 803 Schenkel Lane, Frankfort, Kentucky 40601.

Air Pollution Control District of Jefferson County, 850 Barrett Avenue, Suite 205, Louisville, Kentucky 40204.

FOR FURTHER INFORMATION CONTACT: Scott Southwick, Regulatory Planning and Development Section, Air Programs Branch, Air, Pesticides & Toxics Management Division, Region 4 Environmental Protection Agency, 345 Courtland Street, NE, Atlanta, Georgia 30365. The telephone number is 404/347–3555, x4207.

SUPPLEMENTARY INFORMATION: On November 6, 1991 (56 FR 56694), EPA designated portions of Oldham and Bullitt Counties as moderate O_3 nonattainment. Sections 107(d)(4)(A)(i) and (ii) of the 1990 Clean Air Act Amendments (CAAA) set out the general process by which areas were to be designated for O_3 attainment/nonattainment immediately after enactment of the CAAA. Under the CAAA, preenactment O_3 and carbon monoxide (CO) nonattainment areas were classified on the date of enactment according to the severity of their problem. Within 120 days of enactment of the CAAA, the Governor of each state was required to submit a list of areas within the state, designating each area as attainment, nonattainment, or unclassifiable (120-day letter). Within 60 days of submitting the state lists, EPA was required to notify states of any potential modifications to the state's recommendations and encourage states to comment within 20 days to EPA's proposal. EPA was required to promulgate the lists, including boundary modifications, within 240 days of enactment.

On March 14, 1991, the Commonwealth of Kentucky (the Cabinet) submitted a list of ozone nonattainment, attainment and unclassifiable areas and boundaries. The Cabinet proposed that Jefferson County be the only Kentucky county in the Louisville nonattainment area. EPA gave 60 day notification to the Cabinet on May 13, 1991, that it intended to modify the proposed designation list. Pursuant to section 107(d)(1)(i) of the CAAA, EPA indicated that it intended to include Bullitt and Oldham Counties in the Louisville nonattainment area due to monitored violations of the NAAQS for O_3 in these counties.

On June 3, 1991, the cabinet formally disagreed with EPA's decision to include Bullitt and Oldham Counties in the Louisville nonattainment area. EPA and the Cabinet subsequently agreed to include the portions of Bullitt and Oldham Counties that contained the monitors that recorded the O_3 NAAQS violations and the sources whose emissions contributed to the O_3 NAAQS violations. Partial boundaries were developed and EPA published the nonattainment designation for the Louisville area on November 6, 1991 (FR 56 56694). Natural boundaries, roads, powerlines, etc., were used to detail the nonattainment area. When these boundaries were developed, sources on one side of the street or intersection were included in the nonattainment area while sources on the other side inadvertently were not. As a result, not all sources contributing to the violation of the O_3 NAAQS in Louisville were included in the nonattainment area, and inequitable economic impacts have been placed upon small competing businesses. This has affected the well being of some small businesses and it has undermined the effectiveness of the plan to attain the standard in the Louisville nonattainment area.

Final Action

In the Federal Register of November 6, 1991 (56 FR 56694), EPA issued a final rule promulgating the designations, boundaries, and classifications of O_3 nonattainment areas (and for nonattainment areas for other pollutants not addressed in this action). Pursuant to section 110(k)(6) of the CAAA, EPA is correcting the boundary of the Kentucky portion of the Louisville moderate O_3 nonattainment area to extend the nonattainment area 750 ft. outward from the center of a road or intersection.

Under section 307(b)(1) of the Act, 42 U.S.C. 7607 (b)(1), petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 20, 1995. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2) of the Act, 42 U.S.C. 7607(b)(2).)

The OMB has exempted this action from review under Executive Order 12866.

Under the Regulatory Flexibility Act, 5 U.S.C. 600 *et seq.*, EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.